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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,190	12/14/2000	Tetsuo Shibuya	14043 (JP919990270US1)	9159
7590 12/02/2005 SCULLY, SCOTT, MURPHY & PRESSER 400 Garden City Plaza Garden City, NY 11530			EXAMINER LY, CHEYNE D	
			ART UNIT 2168	PAPER NUMBER

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/737,190

Applicant(s)

SHIBUYA, TETSUO

Examiner

Cheyne D. Ly

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2168

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 1, 3-11, and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date November 23, 2005.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicants' arguments filed September 06, 2005 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The addition of claims 13 and 14, and the cancellation of claims 2 and 12 have been acknowledged.
3. Newly submitted claim 13 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
4. The claimed invention as originally presented does not require the limitation of "determining if the same element is present earlier in the target array..." as required by claim 13, steps ii) and iii). It is noted that the preamble of claims 13 and 14 are similar; however, the critical active steps of claim 13 cause said claim to be distinct from the invention recited by claim 14, which is directed to the claimed invention as originally claimed. Therefore, the distinct critical features of claim 13 supports the undue search burden if said claim was examined together with the subject matter of claim 14.
5. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 13 has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
6. Claim 14 is examined on the merits.

**LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining complementary strands of a DNA or an RNA molecule, does not reasonably provide enablement for determining the “an element in the target array that is a given complement to said first occurrence...” The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

9. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

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10. The instant rejection has been necessitated by the addition of new claim 14.

11. For example, Applicant exemplifies the claimed method for a gene sequence wherein “the A and T or the G and C of DNA complement each other...” (page 4). However, the claim is not limited to a gene sequence. Further, one of skill in the art would have attributed the customary and ordinary meaning of “a universal set, the set of all elements in the set that are not in a specified subset” to the term “complement.” However, the claim does not define the specified subset. The specification does not provide clear guidance or working examples which would enable one of skill in the art to determine a “complement” when a specified subset has not been defined. A reasonable interpretation of claim 14 is that the element of the target array has an infinite number of complements because the specified subset has not been defined. Therefore, one of skill in the art would require undue experimentation to predictably practice the claimed method in regard to the limitation of “an element in the target array that is a given complement to said first occurrence...”

## **RESPONSE TO ARGUMENTS**

12. Applicant argues claim 14 satisfies the enablement requirement of 35 U.S.C. 112, first paragraph. Applicant’s argument is not persuasive as discussed above.

## **CLAIM REJECTIONS - 35 USC § 101**

13. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Claim 14 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter.

15. The instant rejection has been necessitated by claim amendments.

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16. It is noted that the limitation of “array” has been reasonably construed as “a rectangular arrangement of quantities in rows and columns, as in a matrix” (dictionary.com).

17. Claim 14 is rejected because the claimed subject matter is directed to a mathematical algorithm. The claimed invention as recited by claim 14 is nonstatutory because the claimed invention is specifically directed to the manipulation of a mathematical array. Therefore, the claimed invention being limited to an abstract idea such as a mathematical array is not patentable (MPEP § 2106 (IV)(B)(1)).

#### **RESPONSE TO ARGUMENT**

18. On page 13, Applicant argues that claim 14 “positively set forth a step of analyzing the structure of the target array,” which is “a practical, tangible, and useful result, and is statutory subject matter within the meaning of 35 U.S.C. 101.” Applicant’s argument is not persuasive because the claimed invention is specifically directed to the manipulation of a mathematical array. For example, the claimed method consists solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process. Therefore, the claimed invention as recited claim 14 does not result in “a practical, tangible, and useful result.”

#### **CONCLUSION**

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until

after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. This application contains claims 1, 3-11, and 13 drawn to an invention nonelected without traverse, filed February 10, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

22. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

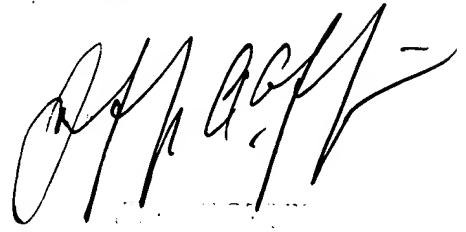
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23. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The USPTO's official fax number is 571-272-8300.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Gaffin, can be reached on (571) 272-4146.

C. Dune Ly  
Patent Examiner  
11/23/05



JEFFREY GAFFIN